TOTOKU

JUN - 7 2004

510(k) SUMMARY

K040695

Submitter Information:	TOTOKU ELECTRIC CO., LTD. 300 Oya, Ueda Nagano 386-0192 Japan
Contact Person:	Mikio Hasegawa, General Manager Email: hasegawam@totoku.co.jp Tel:+81.268.34.5469 Fax:+81.268.34.5548
Date Prepared:	March 15, 2004
Device Name:	21.3-inch (54cm) Monochrome LCD Monitor ME213L (MDL2108A)
Common Name:	ME213L, MDL2108A, 2M Monitor/Display
Classification Name:	Class II (Part 892 Radiology Devices Sec. 892.2050 Picture Archiving and Communication System)
Predicate Device:	MDL2004 (K021738)
Device Description:	Best suited for CT and MRI, ME213L (MDL2108A) is a 21.3-inch high definition monochrome medical imaging LCD monitor with higher luminance (1500cd/m^2) and longer lifetime (three times as long as our existing models). With λ-Sentinel, a luminance stabilizing circuit, mounted, ME213L (MDL2108A) delivers stable display of images.
Indended Use:	21.3-inch (54cm) Monochrome LCD Monitor ME213L (MDL2108A) is to be used in conjunction with the picture archiving communication systems (PACS) for medical imaging applications. It is not meant to be used for digital mammography.
Substantial Equivalence:	ME213L (MDL2108A) shares the same characteristics with our predicate device MDL2004 (K021738) except for the panel which is superior to the predicate device in display area, luminance, and number of photo sensors available. It also has a three-times longer lifetime.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 7 2004

Mr. Mikio Hasegawa
General Manager
Totoku Electric Co., Ltd.
MM Company, Design Group
300 Oya, Ueda,
Nagano 386-0192
JAPAN

Re: K040695
Trade/Device Name: 21.3-inch (54cm) Monochrome LCD Monitor ME213L (MDL2108A)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: March 15, 2004
Received: March 17, 2004

Dear Mr. Hasegawa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: Not Known K040695

Device Name: 21.3-inch (54cm) Monochrome LCD Monitor ME213L (MDL2108A)

Indications for Use:

21.3-inch (54cm) Monochrome LCD Monitor ME213L (MDL2108A) is to be used in conjunction with the picture archiving communication systems (PACS) for medical imaging applications. It is not meant to be used for digital mammography.

Prescription Use ✓ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040695